

29. (amended)

A method of enhancing the delivery of oil soluble skin care actives into the skin from the oil phase of a topical water-in-oil emulsion composition comprising, applying said topical composition to the skin, said topical composition's oil phase comprising:

- i) a silicone elastomer; and
- ii) an oil-soluble skin care active.

30. (amended)

A method of regulating the condition of skin, said method comprising the step of topically applying to the skin of mammal in need of treatment, a safe and effective amount of the composition comprising an oil continuous phase and an aqueous discontinuous phase, wherein the oil phase comprises:

- a) an oil-soluble skin care active;
- b) a silicone oil; and
- c) a silicone elastomer.

31. (amended)

The method according to claim 30 wherein the composition comprises an oil continuous phase and an aqueous discontinuous phase, wherein the oil phase comprises: an oil-soluble skin care active;

- a) a silicone oil; and
- b) a silicone elastomer.

#### REMARKS

##### Application Amendments

By the amendments presented, Claims 1-26 have been cancelled in order to forward prosecution of pending method claims 27-31. No additional claims fee is due as a result of these amendments.

##### Invention Synopsis

This invention relates to the field of water-in-oil emulsion compositions containing silicone elastomers. More particularly, this invention relates to a method of using water-in-silicone emulsion compositions containing silicone elastomers that exhibit enhanced delivery of oil-soluble skin care actives into the skin. Without being limited by theory, it is believed

that the oil-soluble skin care active may be stably formulated into the silicone oil phase with the aid of the silicone elastomer, wherein both the silicone oil and silicone elastomers create a non-preferable environment for the oil-soluble skin care active. Upon applying such compositions to the skin, the oil-soluble skin care active partitions out of the silicone-containing phase of the emulsion and is delivered into the skin. By partitioning out of the silicone oil phase, oil-soluble active delivery into the skin is greatly enhanced over active in a conventional oil phase wherein the active tends to remain solubilized in the oil and does not partition out onto the skin.

### Art Rejections

#### §102 Rejections

(a) Rouquet et al.

Claims 27, 29 and 30 have been rejected under 35 USC §102(b) as being anticipated by, or in the alternative, under 35 USC §103(a) as obvious over Rouquet et al. (EP 0908175) (EP '175). The Examiner contends that Rouquet inherently teaches this enhanced delivery method claimed herein. Applicants respectfully traverse this rejection as it would apply to the claims as amended herein.

EP '175 relates to both oil-in-water and water-in-oil compositions comprising elastomeric organopolysiloxanes wherein according to the translation of the French language document provides high levels of spherical particles that does not result in unstable compositions characterized by high levels of organopolysiloxane particles that results in non-homogeneous appearing compositions that suffer from precipitation and flocculation of the silica-based particles after periods greater than 2 months at 45°C (see page 2, paragraph 2 and page 3, the definition of "stable composition"). The stability of such particles is important since these particles are relied upon to absorb oils while not drying on the skin, therein maintaining good cosmetic properties.

Notwithstanding the enhanced cosmetic stability advantages provided by the compositions disclosed by Rouquet, there is no teaching that such compositions also provide a significant skin care active delivery benefit. No distinction or advantage is taught in the context of a water-in-oil composition as is now a limitation of the pending claims.

Given the foregoing considerations, it is submitted that Applicants' claims as now amended are not anticipated by, nor rendered obvious over, EP '175. Accordingly, rejection of these claims over, under 35 USC §102(b) is improper and should be withdrawn.

(b) Mohammadi.

Claims 27, 29-30 have been rejected under 35 USC §102(e) as being anticipated by, or in the alternative, under 35 USC §103(a) as obvious over Mohammadi (US 6,217,913).

(Mohammadi). The Examiner contends that Applicants respectfully traverse this rejection, as it would apply to the claims as amended herein.

Mohammadi relates to cosmetic compositions comprising an active that is a gorgonian extract, a crosslinked polysiloxane elastomer, a surfactant, and a carrier. The extract is water-soluble as is evident by table 1 phase E of the examples shown therein. Furthermore, the patentee states at the top of column 3 that the compositions disclosed therein have substantial levels of water. On the basis of these teachings, clearly the active is not intended to be delivered via a silicone oil phase of the composition as is claimed in the pending method claims.

Given the foregoing considerations, it is submitted that Applicants' claims as now amended are not anticipated by, nor rendered obvious over, Mohammadi. Accordingly, rejection of these claims over, under 35 USC §102(b) is improper and should be withdrawn.

(c) Sine et al.

Claims 27, 29-30 have been rejected under 35 USC §102(e) as being anticipated by, or in the alternative, under 35 USC §103(a) as obvious over Sine et al. (US 6,217,913) (Sine). The Examiner contends that Applicants respectfully traverse this rejection as it would apply to the claims as amended herein.

Sine relates to compositions comprising sanitizing agent, moisturizing agent, degreasing agents, thickeners, humectants, perfumes, and from 0-60% water.

Given the foregoing considerations, it is submitted that Applicants' claims as now amended are not anticipated by, nor rendered obvious over, Sine. Accordingly, rejection of these claims over, under 35 USC §102(b) is improper and should be withdrawn.

§103 Rejections

a) Rouquet et al.

Claims 1, 3, and 11 have been rejected under 35 U.S.C. §103(a) as unpatentable over Rouquet et al. (EP 0908175) (EP 175). The Examiner contends that it would have been obvious to and thereby arrives at the Applicants' invention. The above amendment has cancelled these claims and thus the pending rejection is moot in light of such amendment.

b) Mohammadi

Claims 1, 5, and 8 have been rejected under 35 U.S.C. §103(a) as unpatentable over Mohammadi. (US 6,217,913) (Mohammadi). The Examiner contends that it would have been obvious to and thereby arrives at the Applicants' invention. The above amendment has cancelled these claims and thus the pending rejection is moot in light of such amendment.

## c) Sine et al.

Claims 27, 29-30 have been rejected under 35 U.S.C. §102(e) or in the alternative §103(a) as unpatentable over Sine et al. (US 6,217,913) (Sine). The Examiner contends that it would have been obvious to and thereby arrives at the Applicants' invention. Applicants respectfully traverse this rejection as it would apply to the claims as amended herein.

Sine relates to compositions comprising sanitizing agent, moisturizing agent, degreasing agents, thickeners, humectants, perfumes, and from 0-60% water. The antimicrobial active material disclosed by Sine include both oil and water-soluble materials, with no preference shown towards either. In fact, reviewing the examples found therein, sine discloses in each of his five examples an antimicrobial, (Quadrol Polyo.I) is according to the processing directions found therein solubilized in water. Clearly that if there is any teaching that is made by Sine regarding delivery of skin care actives, those actives are not delivered from oil. Furthermore, there is no teaching that delivery to the skin is enhanced by when the active is incorporated in the oil phase (rather than the oil phase) as is claimed in the pending method claims of the present invention.

Applicants' claimed invention is distinguishable from the methods of delivering skin care actives as disclosed by Sine. Given the foregoing considerations, it is submitted that Applicants' Claims are not anticipated by or rendered unpatentably obvious by the teachings of the Sine reference. Accordingly, rejection of these claims over this reference under 35 USC §§102(e) and 103(a) are improper and should be withdrawn.

## d) Stepniewski et al.

Claims 27, and 29-30 have been rejected under 35 U.S.C. §103(a) as unpatentable over Stepniewski et al. (US 6,027,738) (Stepniewski). The Examiner contends that it would have been obvious to and thereby arrives at the Applicants' invention. Applicants respectfully traverse this rejection as it would apply to the claims as amended herein.

Stepniewski relates to an anhydrous make-up composition comprising a silicone gel and a silicone-oil base, wherein the silicone gel comprises an organopolysiloxane elastomer dispersed in a silicone-compatible vehicle. Applicants' claimed invention is certainly distinguishable since it is water containing and not anhydrous. Furthermore, there is no teaching by Stepniewski that the active that may be contained therein is advantageously delivered out of the oil phase of an water containing emulsion to enhance delivery of a skin care active resulting in skin care benefits. Accordingly, rejection of these claims over this reference under 35 USC §103(a) is improper and should be withdrawn.

## e) Roquet et al. or Mohammadi or Sine et al. or Stepniewski in view of Beerse et al.

Claims 28 and 31 have been rejected under 35 U.S.C. §103(a) as unpatentable over Roquet et al. or Mohammadi or Sine et al. or Stepniewski in view of Beerse et al. (US 6,294,186) (Beerse). The Examiner contends that it would have been obvious to and

thereby arrives at the Applicants' invention. Applicants respectfully traverse this rejection as it would apply to the claims as amended herein.

As is the case of the above references, none of the previously cited references provide a teaching preferring the method claimed herein wherein delivery is enhanced due to the way the composition is constructed, resulting in the partitioning out of the actives from the composition upon applying to the skin. Similarly, Beerse fails to disclose such a method for enhancing delivery of actives. While there is a teaching of using antimicrobial actives in water-in-silicone emulsions, there is additionally a teaching wherein water-in-silicone emulsions, water-in-oil emulsions or oil-in-water emulsions are all interchangeable carriers with none of them providing delivery advantages over any of the others.

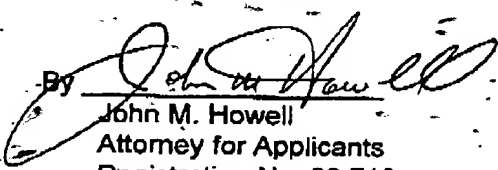
Given the foregoing considerations, it is submitted that Applicants' Claims 28 and 31 are not rendered unpatentably obvious by the combined teachings of the Roquet et al. or Mohammadi or Sine et al. or Stepniewski when combined with Beerse. Accordingly, rejection of these claims over this combination of references under 35 USC §103(a) is improper and should be withdrawn.

#### CONCLUSION

Applicants have made an earnest effort to place their application in proper form and to distinguish their invention from the applied prior art. WHEREFORE, Applicants respectfully request the reconsideration of this application, entry of the amendments presented, withdrawal of the rejections under 35 U.S.C. §102 and §103, withdrawal of the double patenting rejection, and allowance of Claims 27-31.

Respectfully submitted,

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February 18, 2003

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**MARKED VERSION SHOWING CHANGES MADE**

27. (amended)

A method of enhancing the delivery of oil-soluble skin care actives into the skin comprising applying to the skin of a mammal in need of treatment, a safe and effective amount of a water-in-oil [the] composition [of Claim 1.] comprising:

a) an oil-soluble skin care active;

b) a silicone oil; and

c) a silicone elastomer.

28. (amended)

The [A] method of enhancing the delivery of oil-soluble skin care actives into the skin according to claim 27 wherein the composition's [comprising, applying to the skin of a mammal in need of treatment, a safe and effective amount of the a composition of Claim 13.] oil continuous phase comprises:

a) an oil-soluble skin care active;

b) a silicone oil; and

c) a silicone elastomer.

29. (amended)

A method of enhancing the delivery of oil soluble skin care actives into the skin from the oil phase of a topical water-in-oil emulsion composition comprising, applying said [a] topical composition to the skin, said topical composition's oil phase comprising:

i) a silicone elastomer; and

ii) an oil soluble skin care active.

30. (amended)

A method of regulating the condition of skin, said method comprising the step of topically applying to the skin of mammal in need of treatment, a safe and effective amount of the composition [of Claim 1.] comprising an oil continuous phase and an aqueous discontinuous phase, wherein the oil phase comprises:

a) an oil-soluble skin care active;

b) a silicone oil; and

c) a silicone elastomer.

31. (am nded)

The [A] method according to claim 30 wherein the composition [of regulating the condition of skin, said method comprising the step of topically applying to the skin of mammal in need of treatment, a safe and effective amount of the composition of Claim 13.] comprises an oil continuous phase and an aqueous discontinuous phase, wherein the oil-phase comprises: an oil-soluble skin care active;

- a) a silicone oil; and
- b) a silicone elastomer.